

# Introduction of ICD-11 in Germany: Seizing opportunities together

## ICD-11 Einführung in Deutschland: Gemeinsam die Chance nutzen



### Authors

Karl Broich<sup>1</sup>, Johanna Callhoff<sup>2, 3</sup>, Peter Kaskel<sup>4</sup> , Christoph Kowalski<sup>5</sup>, Jürgen Malzahn<sup>6</sup>, Christine Mundlos<sup>7</sup>, Christoph Schöbel<sup>8</sup>

### Affiliations

- 1 Leitung, Bundesinstitut für Arzneimittel und Medizinprodukte, Bonn, Germany
- 2 Deutsches Rheuma-Forschungszentrum Programmbereich Epidemiologie & Versorgungsforschung, Arbeitsgruppe Versorgungsforschung, Deutsches Rheuma-Forschungszentrum Berlin, Ein Institut der Leibniz-Gemeinschaft, Berlin, Germany
- 3 Institut für Sozialmedizin, Epidemiologie und Gesundheitsökonomie, Charité – Universitätsmedizin Berlin, Berlin, Germany
- 4 Market Access, Idorsia Pharmaceuticals Germany GmbH, München, Germany
- 5 Zertifizierung, Deutsche Krebsgesellschaft e.V., Berlin, Germany
- 6 Geschäftsbereich Versorgung, Abteilung Stationäre Versorgung & Rehabilitation, AOK Bundesverband, Berlin, Germany
- 7 Wissensnetzwerk und Beratung, Allianz Chronischer Seltener Erkrankungen (ACHSE) e.V., Berlin, Germany
- 8 Schlafmedizinischen Zentrum, Ruhrlandklinik, Westdeutsches Lungenzentrum am Universitätsklinikum Essen gGmbH, Universitätsmedizin Essen, Essen, Germany

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Georg Thieme Verlag KG, Rüdigerstraße 14,  
70469 Stuttgart, Germany

### Correspondence

Dr. med. MBA Peter Kaskel  
Idorsia Pharmaceuticals Germany GmbH  
Market Access  
Dachauer Straße 63  
80335 München  
Germany  
kaskel@derma.de

### ABSTRACT

With the new ICD-11 developed by the WHO and translated into German for use in Germany by the Federal Institute for Drugs and Medical Devices, the German healthcare system is facing a change that is more than a simple change of a medical coding system. The ICD-11 modernises the coding system, for example, by including new, separate health conditions such as sleep-wake disorders and conditions related to sexual health, thus making the corresponding diseases more visible. The ICD-11 is more precise than the ICD-10: it allows cross-referencing between diagnoses, symptoms, functionality and locations and partially abandons the strict hierarchy of the ICD-10. In addition, a greater number of rare diseases are represented with their own specific code than was previously possible with ICD-10. Finally, the ICD-11 is also significantly more “modern” than the ICD-10 (which dates back to pre-digital times) in that it enables new, digitally-supported processes, such as keywords flexibility and sustainability when updating the system as well as actual coding at the point of care. The switch to ICD-11 can

be a great opportunity for the German healthcare system that should not be missed. It will benefit health service research, which at best will be able to work with much more detailed and correct data sets. But medical care will also benefit because the ICD-11 reflects current medical knowledge. In addition, certain illnesses will be removed from the psychiatric category, meaning that those affected will no longer be stigmatised by their classification in the ICD. The improved coding of diagnoses will ultimately also support guideline-based treatments. However, the changeover is only the first step. The challenges – also for health service research – include in particular the latency of introduction and uniform use as well as the necessary change in coding habits. For ICD-11 to be a success in Germany, authorities, the medical profession, payers and patients must work together on strategies to ensure not only a rapid but also a comprehensive implementation that maximises the potential of ICD-11.

### ZUSAMMENFASSUNG

Mit der von der WHO erarbeiteten und für Deutschland durch das BfArM in deutscher Übersetzung bereitgestellten neuen ICD-11 steht dem Gesundheitssystem eine Umstellung bevor, die mehr ist als ein einfacher Wechsel eines medizinischen Kodiersystems. Die ICD-11 modernisiert die Kodiersystematik zum Beispiel dahingehend, dass neue, separate Gesundheitszustände – Schlaf-Wach-Störungen und Bedingungen im Zusammenhang mit sexueller Gesundheit – aufgenommen und die entsprechenden Erkrankungen damit besser sichtbar werden. Die ICD-11 ist präziser als die ICD-10: Sie erlaubt Querverbindungen zwischen Diagnosen, Symptomen, Funktionen und Lokalisationen und gibt die strenge Hierarchisierung der

ICD-10 in Teilen auf. Außerdem werden mehr Seltene Erkrankungen mit einem eigenen, spezifischen Code abgebildet als dies bisher der ICD-10 ermöglicht hat. Schließlich ist die ICD-11 auch deutlich „moderner“ als die (noch aus vordigitalen Zeiten stammende) ICD-10. Sie ist insofern moderner, als sie neue, digital unterstützbare Prozesse ermöglicht, zum einen soweit es die Aktualisierung der Systematik – Stichworte Flexibilität und Nachhaltigkeit – betrifft, zum anderen in Bezug auf das eigentliche Kodieren am Point-of-Care. Der Umstieg auf die ICD-11 kann für das deutsche Gesundheitswesen eine große Chance sein, die gemeinsam ergriffen werden sollte. Profitieren wird die (Versorgungs-)Forschung, die im besten Fall mit sehr viel detaillierteren und korrekteren Datensätzen arbeiten kann. Aber auch die medizinische Versorgung hat einen Nutzen, weil die ICD-11 den aktuellen Stand des medizinischen Wissens abbildet. Außerdem werden bestimmte Erkrankungsentitäten aus dem bisherigen psychiatrischen Kontext herauslöst, die Betroffenen somit nicht mehr über die Zuordnung in der ICD stigmatisiert werden, und weil mit der besseren Kodierbarkeit von Diagnosen letztlich auch die Voraussetzungen für leitlinienbasierte Therapien verbessert werden. Ein Selbstläufer wird der Umstieg aber nicht. Als Herausforderungen – auch für die Versorgungsforschung – sind insbesondere die Latenz von Einführung und gleichförmiger Nutzung sowie die erforderliche Änderung von Kodiergewohnheiten zu nennen. Damit die ICD-11 in Deutschland ein Erfolg wird, müssen daher alle Anwendungsfelder gemeinsam an der Einführung arbeiten. Behörden, Ärzteschaft, Kostenträger und Betroffene müssen gemeinschaftlich über Strategien nachdenken, wie eine nicht nur zügige, sondern auch umfassende Einführung gelingt, mit der sich die Potenziale, die in der ICD-11 stecken, bestmöglich heben lassen.

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## From ICD-10 to ICD-11

The International Classification of Diseases, the ICD, is the central reference classification in the family of international classifications of the World Health Organisation (WHO) [1]. It enables diseases to be recorded independently of the respective national language. The ICD is a central pillar of billing systems in many countries. It is used in the context of pharmacovigilance and quality assurance. It forms the basis for morbidity and mortality statistics at many different levels. It is used for care management. And it enables comparisons of morbidity and mortality data across institutions, regions, countries and historical periods.

The ICD-10, which was adopted in the mid-1990s, has been used worldwide for all these purposes in recent decades. It had its strengths because it was more comprehensive than the previous version, but its considerable weaknesses have also become increasingly apparent [2]. It was not developed in the digital era, which

means that it does not utilise the full potential of a modern coding system. Fundamental changes to the international version are barely possible anymore, as the WHO has planned further development for emergency codes only (e. g., for Covid-19). Internationally, the uncoordinated, non-compliant expansion of the ICD-10 catalogue by individual nations is a further problem, as this impairs the international comparability of ICD-coded data.

The ICD-11 [3] aims to eliminate these deficits. It is nothing less than a “reset of the system”, according to the WHO in 2018 [2]. The ICD-11 is designed as a relational database which, continues to enable hierarchical coding as before, but can additionally map a variety of relationships between diseases, symptoms, functions and body sites (see info box). Unlike in ICD-10, an element can be assigned to several higher-level elements.

### INFO BOX: THE ICD-11 AS AN AGILE, LEARNING SYSTEM WITH ONTOLOGICAL INFRASTRUCTURE [4]

- **Few master codes and many extension codes** enable precise coding via digital recording
- **Foundation:** Standardised basis that is to be further developed jointly and can incorporate current medical and cultural developments
  - Hierarchical organisation into medical units (multidimensional, i. e. diseases, disorders, injuries, external causes, signs and symptoms), which can optionally be further defined with attributes (body site, body system and causal mechanism)
  - An element can be assigned to several higher-level elements (multi-parenting)
  - Completely electronic, real-time updates
- **Linearisation:** Extracts as statistical classification with clear hierarchical tree structure for coding (single-parenting)
  - Annual update

#### ICD-10-GM

G40-G47 Episodic and paroxysmal diseases of the nervous system  
 G47.- Sleep disorders  
 G47.0 Disorders of initiating and maintaining sleep

F51.- Non-organic sleep disorders  
 F51.0 Non-organic insomnia

#### ICD-11

07 Sleep-wake disorders

- Insomnia
  - 7A00 Chronic insomnia [possible translation]
  - 7A01 Short-term insomnia
  - 7A0Z Insomniac disorders, unspecified

► **Fig. 1** Insomnia in the ICD-10 German Modification (-GM) and ICD-11 (Fig. based on data from [7, 8]).

## Objectives and innovations of ICD-11

A distinction must be made between the formal/procedural and medical/content-related objectives of the ICD-11. Formal and procedural are among the goals of the WHO [5, 6],

- To utilise the digital possibilities from the point of care to the statistical analysis of data to achieve a more flexible and long-lasting classification system, including annual updates, whereby the established processes and experience with the annual updates of ICD-10 German Modification (-GM) were expanded and supplemented for input from the general public
- To enable the use of digital tools to support coding in everyday life,
- To improve data quality,
- To improve international comparability and
- To make the ICD-11 more robust and adaptable so that national extensions are no longer necessary or can take place within the ICD-11 Foundation.

In terms of content and medicine, the previous Chapter 3 of ICD-10 “Diseases of the blood and haematopoietic organs and certain disorders involving the immune system” has been divided into Chapter 3 “Diseases of the blood or blood-forming organs” and Chapter 4 “Diseases of the immune system” [7] in ICD-11. However, the addition of two completely new chapters is particularly noteworthy. The first is Chapter 7 “Sleep-wake disorders”, which means that a sleep-wake disorder is no longer classified as a symptom [7].

The second is Chapter 17 “Conditions related to sexual health”, including gender incongruence.

With these chapters, health conditions that were previously categorised as psychological so-called F diagnoses in the ICD-10 are given their own classification. The complex post-traumatic stress disorder (CPTSD) included in the ICD-11 should also be mentioned. This describes a more complex symptom picture and is often associated with repeated or prolonged trauma from which it is difficult or impossible to escape, such as torture, prolonged domestic violence or repeated physical or sexual abuse in childhood, as well as chronic pain syndromes (see ► **Fig. 2**), which have been summarised in a chapter (MG30) for the first time (► **Fig. 2**) [7, 9, 10].

Also new are Chapter 26 “Supplementary Chapter Traditional Medicine Conditions” and Chapter V “Supplementary Section for Functioning Assessment” [7]. In order to ensure consistency with the ICF, the International Classification of Functioning, Disability and Health, the ICF has been incorporated into the ICD-11 Maintenance Platform (e. g., for Intentional Communication, see ► **Fig. 3**) [11].

Chapter X “Extension codes” is also new. The additional codes can be used to describe ICD-11 master codes in more detail – for example with regard to anatomical localisation. It is also possible to add associated information – for example about secondary diseases – to the master code. Due to its diagnostic breadth, the ICD-11 is ideal for specialist care. Its interoperability with standardised medical terminologies used in the hospital setting such as SNOMED CT [14] (see example of Aortic Aneurysm, ► **Fig. 4**), as well as primary care (ICPC-3) [15] is important.

## Status of implementation in Germany

The ICD-11 has been effective and ready for adoption since 1 January 2022, including in Germany. However, it will still be a few years before it arrives in healthcare. An important deadline for the implementation of ICD-11, not only in Germany, is 2027: from then on, deaths should be reported to the WHO in ICD-11 coded form. In Germany, the German translation of ICD-11 has been available since February 2022 [7]. The initial translation process is largely complete (► **Fig. 5**), but quality assurance by the scientific and medical societies is still ongoing.

To ensure the smoothest possible transition to ICD-11, a transition analysis sponsored by the Federal Ministry of Health (BMG) has taken place, the results of which are currently being discussed in the ICD-11 working group of the Board of Trustees for Classification Issues in Healthcare (KKG). Key recommendations for the upcoming changeover planning are

- To ensure the availability of the ICD-11 in German,
- To create a bidirectional transition between ICD-10-GM and ICD-11,

#### ICD-10-GM

##### F40-F48 Neurotic, stress and somatoform disorders

##### F45 - Somatoform disorders

- F45.4- Persistent pain disorder
- F45.40 Persistent somatoform pain disorder
- F45.41 Chronic pain disorder with somatic and psychological factors

##### R50-R69 General symptoms

##### R52.- Pain, not elsewhere classified

- R52.1  
Chronic uncontrollable pain
- R52.2  
Other chronic pain
- R52.9  
Pain, unspecified

#### ICD-11: 21 Symptoms or clinical findings, not elsewhere classified

##### ➤ General symptoms or clinical findings

##### ➤ General symptoms

##### – Pain

##### MG30 Chronic pain

##### ▷MG30.0 Chronic primary pain

##### ▷MG30.1 Chronic tumour-associated pain

##### ▷MG30.2 Chronic post-operative or post-traumatic pain

##### ▷MG30.3 Chronic secondary musculoskeletal pain

##### ▷MG30.4 Chronic secondary visceral pain

##### ▷MG30.5 Chronic neuropathic pain

##### ▷MG30.6 Chronic secondary headache or orofacial pain

##### MG30.Y Other specified chronic pain

##### MG30.Z Chronic pain, unspecified

► **Fig. 2** Chronic pain syndromes in the ICD-10 German Modification (-GM) and ICD-11 (Fig. based on data from [7, 8]).

#### ICD-10-GM and ICF using the example of intentional communication - syndromes, diseases and disorders

Information on associated syndromes, disorders, functional limitations:

- Transcribed developmental disorders of speech and language (F80)
- Stuttering (F98.5), Poluttering (F98.6)
- May also occur with:
  - Limitation of cognition and metacognition
  - Restriction of social-emotional functioning
  - Early childhood autism (F84.0), Autism Spectrum Disorder (ICD-11, Beta draft)
  - Damage to the functions of hearing (b230 Functions of hearing)
  - ADD (F90.0) and ADHD (F90.1)

#### ICD-11 with ICF using the example of intentional communication - syndromes, diseases and disorders

Information of associated syndromes, disorders, functional limitations:

- 6A01 Speech or language development disorders
  - 6A01.1 Developmental speech fluency disorder (stuttering, poluttering)
  - May also occur with:
    - 6A00 Disorders of intellectual development
    - QE0Y Other specified problem related to social or cultural environment
    - 6A02 Autism spectrum disorder
    - V Supplementary section for the assessment of functional capability Model Disability Survey - short version
      - VE01 Hearing and vestibular functions
      - Generic functional domains
      - VV11 Hearing and vestibular functions
    - 6A05 Attention deficit hyperactivity disorder [ADHD]
      - 6A05.0 Attention deficit hyperactivity disorder [ADHD], predominantly unfocussed
      - 6A05.1 Attention deficit hyperactivity disorder [ADHD], predominantly hyperactive-impulsive
      - 6A05.2 Attention deficit hyperactivity disorder [ADHD], combined

► **Fig. 3** Implementation of linking with other coding systems in ICD-11 (vs. ICD-10-GM and ICF) using the example of Intentional Communication (Fig. based on data from [7, 8, 11–13]).

- To initiate further specific transition analyses and prospective studies and
- To draw up a roadmap for the introduction of ICD-11 in Germany.

## Opportunities of ICD-11 from the perspective of research and industry

The progress that ICD-11 can potentially bring for health service research is best illustrated with examples. A typical health service research question in the field of rheumatology is: “What exactly is the standard of care for rheumatoid arthritis (RA) in the population of statutory health insurance (SHI)-insured patients?” To answer this question, it is important to differentiate between seropositive and seronegative RA and whether the serostatus is known at all. It would be inter-

esting to know how the medication is selected regarding the different sites of manifestation of RA and whether and how it is related to secondary diseases of RA. The possibilities offered by ICD-10 for these analyses are limited. Firstly, although the ICD-10 recognises seropositive chronic polyarthritis, seronegative RA only appears much later in the hierarchy and only as a subheading of ‘other chronic polyarthritis’ [8]. It is therefore rarely coded in everyday practice [17]. The ICD-11 offers a clearer structure in this example and makes it possible to specify the location with the help of X codes and to link concomitant diseases regarded as associated with RA with the help of a slash [7]. For example, the ICD-11 code FA20.0&XA86T5 describes a seropositive RA in which the metacarpophalangeal joints are affected. And FA20.0&XA86T5/CB05.1 would signal that there is also an interstitial lung disease associated with the RA. In contrast, ICD-10 would only allow the coding of interstitial lung disease as a parallel code, without the causal link to RA becoming transparent [8].

## SNOMED CT

Disorder of cardiovascular system / Aneurysm

Aneurysm of artery of trunk / Aortic aneurysm

– Aneurysma of thoracic aorta (disorder)

- Aneurysma of aortic arch (disorder)
- Aneurysma of ascending aorta (disorder)
- Perforation of thoracic aorta co-occurrent and due to aneurysma of thoracic aorta (disorder)
- Thoracic aortic aneurysma which has ruptured (disorder)
- Thoracic aortic aneurysma without rupture (disorder)

• Thoracoabdominal aortic aneurysma

• Thoracoabdominal aortic aneurysma

## ICD-11

Chapter 11: Diseases of the circulatory system

Diseases of the arteries or arterioles

BD50 Aortic aneurysm or dissection

BD50.3 Aneurysm of the thoracic aorta

BD50.30 Aneurysm of the thoracic aorta with perforation

BD50.31 Aneurysm of the thoracic aorta with rupture

BD50.32 Aneurysm of the thoracic aorta without indication of perforation or rupture

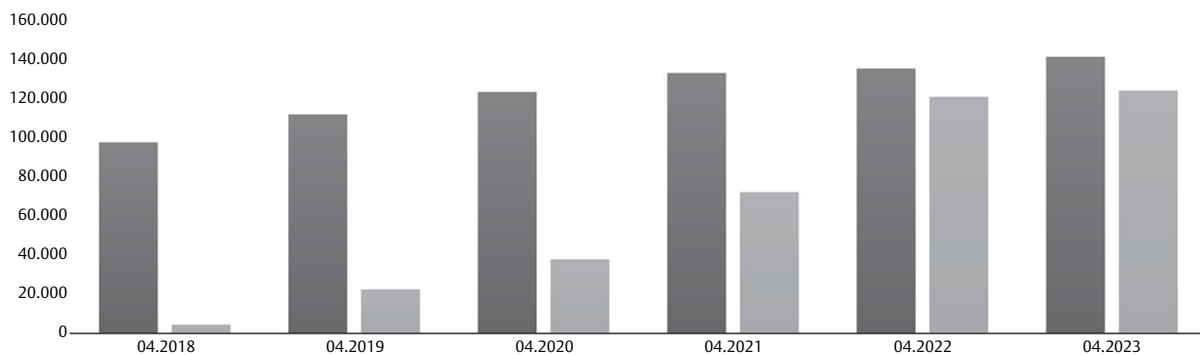
BD50.3Y Other specified aneurysm of the thoracic aorta

BD50.3Z Aneurysm of the thoracic aorta, unspecified

BD50.4 Aneurysm of the abdominal aorta

BD50.5 Thoracoabdominal aortic aneurysm

► **Fig. 4** Aortic Aneurysm from SNOMED CT – ICD-11 harmonisation (Fig. based on data from [7, 16]). The SNOMED CT concept “Aneurysm of the thoracic aorta” is matched with ICD-11 code BD50.3Z (“Aneurysm of the thoracic aorta, unspecified”).



► **Fig. 5** Status of the translation of ICD-11 into German.

The example shows that ICD-11 allows coding at a level of detail that would be a huge step forward for health service research. However, it also shows how complex the ICD-11 can be and how great the need is for solutions that support documentation performed by the end users at the point of care – especially in a digital way – in the treating institutions. The usage of ICD-11 in outpatient and inpatient routine care can only be recommended by means of digital applications – but this is exactly what the ICD-11 was developed for.

From the perspective of the healthcare industry, the advantages of ICD-11 compared to ICD-10 are similar to those of health service research. Relevant questions for drug development and drug sales can hardly be answered based on ICD-10 data or conventional billing data, at least for some diseases. For example, in adults with lung cancer, only 25 % of cases could be clearly identified as small cell or non-small cell lung cancer based on German health insurance datasets, and this rate was only achieved when the medication was ana-

lysed in addition to the ICD-10 coding [18]. In addition, ICD-11-based coding would make the evidence base for calculating the total number of patients affected in the AMNOG transparent and comprehensible and help to significantly improve planning.

## Opportunities from the perspective of medical care

It is not only research that benefits from the ICD-11, but also the direct care of those affected. The two newly included chapters “Sleep-wake disorders” and “Conditions related to sexual health” are an important step forward here. Many people do not realise it, but classifications can have a very direct influence on how certain illnesses are perceived in a healthcare system. In the case of sleep-wake disorders and conditions related to sexual health, this has

meant that conditions in these areas often do not receive the attention they deserve.

This can be illustrated by insomnia disorder, a disorder that affects around 6 % of the adult population [19, 20]. The chronic form of this disorder, chronic insomnia, is characterised by difficulty falling asleep and/or sleeping through the night at least three times a week for at least three months, which is accompanied by significant distress and/or impairment during the day. Insomnia was first classified as an independent disorder in the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders) in 2013 [21, 22] and was adopted in the ICSD-3 (International Classification of Sleep Disorders) [23]. Prior to this, insomnia was not considered a separate disorder, but was largely seen as a symptom of other illnesses or dismissed as a mood disorder. In the ICD-10, short-term insomnia is shown in Chapter VI “Diseases of the nervous system” as “Episodic and paroxysmal disorders”. In contrast, chronic insomnia, like other sleep disorders, is classified in Chapter V “Mental and behavioural disorders”. Accordingly, patients receive an F diagnosis when coding, specifically F51.0 “Nonorganic sleep disorders” (► **Fig. 1**) [8].

This classification as an F diagnosis is problematic because it is associated with the stigmatisation of those affected as “mentally ill”. The consequence of the fear of stigmatisation is that chronic insomnia is not even coded in cases of doubt. The fact that this actually happens is illustrated by the 2019 health report from the SHI Barmer [24]. The researchers found a strong divergence between the frequency of reported sleep problems and the actual documentation of these problems reported as a medical F51.0 diagnosis: only around one in four people who reported relevant insomnia had also received a medical diagnosis in this study [24]. However, only time will tell whether the new classification system with a separate chapter on “sleep-wake disorders” will help to catalyse a change in behaviour.

This is scientifically unsatisfactory because chronic insomnia disorder is systematically underrepresented in statistics as a result. Furthermore, it is also highly problematic from a healthcare perspective because a formal diagnosis is only available if it can be adequately coded, based on which suitable and, above all, reimbursable therapies can then be initiated. The ICD-11 will therefore contribute to greater visibility in the case of chronic insomnia disorder and therefore indirectly to better treatment. The same applies to gender medicine [25], the problem of abuse [9, 10], and to pain medicine [26].

## The patients’ perspective

The example of chronic insomnia disorder shows that coding is not just an abstract billing and healthcare research topic, but can have direct relevance for patients and their environment, i. e., those affected. Another example that illustrates this is the approximately 8000 known rare diseases, of which only around 500 are categorised as separate codes in ICD-10 [8]. Here, too, the ICD-11 will lead to greater visibility [7, 27, 28], not least because – also due to the planned regular updates – more diseases will become codable in the future, thus appearing in the general statistics and also becoming more accessible for health service research on the other.

In the case of rare diseases in particular it is not only about visibility, but also about patient-relevant aspects such as prompt, accurate

diagnosis and needs-based therapeutic and nursing care at various levels. In the immediate care context, it is often not so much the ICD diagnosis that is relevant, but rather the adequate treatment of symptoms and/or functional limitations, depending on the diagnostic or therapeutic context. For this reason, the National Action Plan for People with Rare Diseases (NAMSE) published by the National Action Alliance for People with Rare Diseases in 2013 envisages the coding of rare diseases using Orpha codes as measure 19 and a web-based diagnostic tool for primary care providers as measure 20. This was followed by a national project “Coding of Rare Diseases” from 2013 to 2019, in which the non-classifying diagnosis code Alpha-ID, which was introduced in Germany in 2005 based on ICD-10 [29], was supplemented by Orpha codes. In 2019, the German Federal Joint Committee (G-BA) decided in its resolution on subsidies for centres for rare diseases [30] that coding with Alpha-ID and Orpha code (Alpha-ID-SE) [36] is a quality requirement. The Digital Care and Nursing Modernisation Act [32] then made Alpha-ID-SE coding mandatory for inpatients from 2023. This is a great success for the field of rare diseases. However, there is still no obligation to code in the outpatient sector, and medical documentation and coding are not linked in hospitals either, resulting in a very heterogeneous structure. To make matters worse, hospitals use different software for individual components (e. g. patient administration system/ clinical workplace system/ medical coding software), and the previous ICD-10-GM [8] continues to serve as the basis for billing using German Diagnostic Related Groups (G-DRGs) [33] and for statistical purposes. The Alpha-ID is also a national, parallel system to the ICD, which must be constantly expanded. However, the findings from the Alpha-ID-SE [31] introduction in the inpatient sector can be regarded as a test run for the changeover from ICD-10 to ICD-11 in Germany for the field of rare diseases. A coding system such as ICD-11 is of great value, since it maps rare diseases far more comprehensively than ICD-10, it enables a better linking of symptoms, diagnoses, functionality and concomitant diseases, and it can form the basis for digital applications for symptom-related diagnostic support or software solutions that digitally implement therapeutic pathways. The expectation for ICD-11 is that it will be easier to implement in different healthcare contexts in the future. Of particular importance with regard to rare diseases is the further development of coding in primary care. This is because it is local care that has to pave the way for the 35 current centres for rare diseases in Germany with their special outpatient clinics and that plays an important role in the coordination of care. It therefore appears necessary to switch to a uniform, standardised system across sector boundaries. The ICD-11 offers this opportunity.

## The reimbursement perspective

From a payer perspective, the migration from an ICD-10 world to an ICD-11 world is a major challenge, not least because ICD codes are used extensively in the German healthcare system for management and reimbursement purposes. This is most obvious and best known in inpatient billing via G-DRGs, which relies almost entirely on ICD coding [33]. Less present in the public perception is the fact that ICD-coded diseases also form the basis for the risk structure equalisation of health insurance funds in the German Federal Health Fund [34]. Accordingly, changes in coding may lead to relevant shifts in cash flows at different levels, which the system must then

deal with; this is not unsolvable but must be considered at an early stage with regard to changeover planning and ICD-11 roadmaps.

The great opportunity of ICD-11 from the reimbursement perspective lies in the improved differentiation options in many areas: More precise coding not only facilitates health service research, as discussed above, but of course also allocation of resources and expenditure control with the aim of improving care across health care sectors. At the same time, however, this is also one of the greatest risks: The potential of ICD-11 will remain untapped if it is not possible to achieve coding of the necessary quality and depth. Incentives for users, and in particular physicians, to familiarise themselves intensively with ICD-11 are currently lacking. In the worst-case scenario, a poorly executed changeover could even lead to a deterioration in coding quality with considerable consequences in many areas of the system. This needs to be actively counteracted using digital aids.

## Some fields of action

Given the complexity of the transition from an old to a new classification system, it seems clear that it is highly advised to address the challenges of such a migration at an early stage. It is important to identify possible obstacles that could lead to delays in the implementation of ICD-11. The potential of ICD-11 can only be leveraged if the changeover leads to more detailed, higher quality documentation. The challenges – also for health service research – include the latency of implementation and uniform level of utilisation as well as the required changes in coding practice. The question is how ICD-11 and thus more focused coding can contribute to improving healthcare across health care sectors, because for the few diseases for which coding of disease severity is already possible in ICD-10 (e. g., stage according to New York Heart Association (NYHA) in heart failure, or stage of renal failure), such coding is used in less than half of the cases in the outpatient setting [35]. Instead, ‘not further classified’ is often coded. However, it needs to be mentioned that in the outpatient setting – in contrast to inpatient care [33] – there is no link between ICD coding and reimbursement.

We will therefore conclude by outlining some areas of action that we highly advise to work on or discuss more intensively. This should be started now, even if the required implementation for mortality as per the WHO Assembly resolution by 2027 may currently still seem far away. As in many other areas, forward-looking action will also pay off here and will help to avoid time-consuming and costly loops in an already dynamic regulatory environment.

- **Creating a common understanding among all stakeholders**  
Ideally, all stakeholders in the healthcare system will agree to use the changeover to ICD-11 to sustainably advance documentation in the German healthcare system. Outpatient care and outpatient specialist medical care (Ambulante Spezialfachärztliche Versorgung, ASV, the ‘third sector’) should also be included here. It is by no means guaranteed that such an agreement will be reached. In this context, it is worth remembering the so-called ‘crocodile bite debate’ when ICD-10 was introduced [36] and the discussions in connection with the introduction of coding guidelines in SHI-accredited medical care [36]. It is clear that a common understanding, even if it were to be achieved, would not be enough. But it would be a good basis for all further endeavors.

- **Planning for digital embedding at an early stage**  
A key success factor for an ICD-11 implementation that goes beyond coding the codes that are absolutely necessary for billing is the digital embedding of the coding in the information systems of outpatient and inpatient care. This must go beyond the provision of a pure thesaurus. Instead, coding suggestions should be derived as automatically as possible from the standard documentation, which then only need to be confirmed or discreetly supplemented by the users. Ultimately, only with such technical implementation will it be possible to achieve lasting acceptance for “deep”, high-quality ICD-11 coding that leverages all the possibilities that ICD-11 offers with regard to research, quality assurance and patient management. The implementation of corresponding tools will not be a definite success. In addition, this technical implementation must also follow the “document only once for all purposes” approach and thus embed ICD-11 in the ecosystem of coding systems for various use cases.
- **Thinking about incentive systems**  
The incentive for the introduction of ICD-11 comes on the one hand from the advantages of the new, current and modern classification itself, which brings an advantage for users simply by using it, and on the other hand from the successful embedding in IT systems in interaction with other coding systems such as SNOMED CT (► **Fig. 4**) [16], so that users ideally do not perceive the changeover or coding as a burden or even do not notice it at all. In this way, most coders could recognise the benefits of higher-quality coding as significant, which would be preferable to conventional incentive systems.
- **Involving medical societies more closely**  
There is a particular need for action when it comes to involving the medical and scientific societies and their umbrella organisation, the Association of the Scientific Medical Societies in Germany (AWMF). Medical societies must be involved in the quality assurance of ICD-11 and its translation, a process that is already underway and is being coordinated by the BfArM. However, they are also important contacts for the implementation of ICD-11, especially at a time when the definition of (ultimately ICD-10/11-based) quality indicators and their automated analysis are becoming increasingly important for healthcare policy. The role of the AWMF is also particularly important with regard to the guidelines, and in particular the National Health Care Guidelines and the Oncological Guidelines Programme of the German Cancer Society, German Cancer Aid and AWMF [37], which can help to raise awareness of the changeover in the medical profession. However, the G-BA is also called upon here with regard to the disease management programmes [38] and ASV [39].
- **Check regulatory framework for ICD-11 compatibility**  
Keyword politics: In general, the ICD-11 should already be factored into upcoming reforms in order to prevent facts being created that have to be revised again in the course of the ICD-11 introduction. This concerns digitisation projects such as the readjustment of the electronic patient record (ePA) from the beginning of 2025 [40]. Harmonisation with other coding systems is necessary to smoothly integrate the ICD-11 into the

ecosystem of coding systems of the ePA. SNOMED CT [16], for example, is the most comprehensive international health terminology. In order to avoid burdening users with multiple coding, the principle of “document only once for all purposes” is also an important goal for the ePA. This common use of coding systems is also required internationally, as can be seen from a statement at the last World Health Assembly in May 2023 [41]. However, it also concerns legislative projects that are more distant from digitalisation, such as the hospital reform, where a future transition to ICD-11 could at least be considered. Another example is the topic of present-on-admission indicators [42], which has been addressed but remained unsolved in healthcare policy since the noughties. They are used to differentiate between diagnoses already existing at the time of admission and those acquired in hospital and are relevant for the assessment of complication rates and the risk assessment of the inpatient case mix, among other things. Here, too, the question arises as to how to deal with this issue, which has been postponed several times and is therefore now a priority from the point of view of some stakeholders, in view of the foreseeable transition from ICD-10 to ICD-11. On the one hand, it does not seem expedient to “postpone” this important element to ICD-11, as it has already been postponed for far too long. On the other hand, it is clear that the transition to ICD-11 will have an impact on these indicators, which should at least be taken into account in planning.

## CONCLUSION

The introduction of ICD-11 can be a great opportunity for the German healthcare system on several levels. Firstly, it can lead to significantly more detailed coding, which will enable a more comprehensive utilisation of the data. Secondly, the ICD-11 will modernise the disease catalogue in several areas. Diseases that previously did not appear in the ICD at all, including many rare diseases, will in future be able to be mapped and coded in the regular system. In addition, sleep-wake disorders and conditions related to sexual health will be given their own headings and thus lose the stigma that was previously attached to them due to their historical categorisation as F diagnoses. In order to realise the medical, scientific and healthcare policy potential of ICD-11, the topic should be given high priority at the level of healthcare policy, specialist societies, supervisory authorities and the software industry. With a view to the planned latest introduction date for mortality in 2027, it is necessary to determine which measures should be taken in which order to ensure the simplest possible coding at the point of care from the outset. In the best case this will be perceived by the users themselves as progress and not as another additional bureaucratic imposition, which will help to ensure that resources can be allocated sensibly in the German healthcare system and thus that care in the interests of those affected and their social environment will also be guaranteed in the future.

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